

UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF MASSACHUSETTS

United States of America  
ex rel. Jeffrey J. Bierman,

Plaintiff,

v.

Orthofix International N.V., et al.,

Defendants.

Civil Action No. 05-10557 (EFH)

United States of America  
ex rel. Marcus Laughlin,

Plaintiff,

v.

Orthofix International, N.V., et al.,

Defendant.

(formerly Civil Action No. 1:08-cv-11336  
(JLT))

LEAVE TO FILE GRANTED  
SEPTEMBER 21, 2010

**DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS RELATOR  
MARCUS LAUGHLIN'S SECOND AMENDED COMPLAINT AND OPPOSITION TO  
RELATOR LAUGHLIN'S MOTION FOR LEAVE TO AMEND**

Relator Marcus Laughlin's Second Amended Complaint (the "SAC") asserts theories of liability that have no basis in law, fails to allege facts to support essential elements of Relator's claims, and fails to allege the circumstances of defendants' alleged fraud or any false claims or statements with the specificity required by Federal Rule of Civil Procedure ("Rule") 9(b). For all these reasons, Defendants Orthofix, Inc. and Orthofix International NV ("Defendants" or "Orthofix") moved to dismiss the SAC. Relator's Response To Motion To Dismiss And Motion For Leave To Amend (the "Opposition") does not contest most of the Defendants' arguments for dismissal. Where it does address Defendants' arguments, the Opposition ignores, misconstrues

or simply fails to satisfy controlling First Circuit standards. The exhibits that Relator attached to his Opposition not only do not support the allegations in the SAC, but in fact demonstrate that Relator has no additional facts that he could add to the SAC to cure any of its many defects. Despite several opportunities to amend, Relator has repeatedly failed to file a complaint that meets the most basic pleading requirements of the Federal Rules. At this point it would clearly be futile to allow further leave to amend. Accordingly, the SAC should be dismissed with prejudice and without leave to amend.

### ARGUMENT

#### **I. Counts 1–5 And 7–56 Should Be Dismissed Because Relator Has Not Pled The Circumstances of any FCA Violation or any False Claims with the Specificity Required by Rule 9(b), Despite Repeated Opportunities To Do So**

It is black letter law in the First Circuit that a relator must plead both the circumstances of an alleged FCA violation and the allegedly false claims or false statements with *particularity* in order to survive a motion to dismiss.<sup>1</sup> Thus, in *Karvelas*, the First Circuit upheld dismissal of a complaint that pled fraud theories, but did not allege details of any false or fraudulent claim, any identification numbers or amounts charged, the identify of the individuals allegedly involved in improper practices, or any specific certifications that were false. *United States ex rel. Karvelas v. Melrose Wakefield Hosp.*, 360 F.3d 220, 233–34 (1st Cir. 2004). In *Gagne*, the First Circuit upheld dismissal of a complaint that named the alleged beneficiaries of defendants’ fraud, the

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<sup>1</sup> For claims under section 3729(a)(1), Relator must identify, with particularity, the claims that Orthofix submitted to the government that were allegedly false, including details such as their dates, identification numbers, and amounts. *See United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 46 (1st Cir. 2009); *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000). For claims under sections 3729(a)(2) and (a)(3) (Counts 7 and 9), Relator must identify, with particularity, the false or fraudulent representation that Orthofix allegedly made and the details of the planned false claim that was the object of that representation. *Gagne*, 565 F.3d at 46–48. The circumstances of any alleged fraud must also be pled with particularity under all three of these sections. *See id.* at 45.

statutory source of the funds at issue, the employees of defendant who engaged in certain practices, and relevant loan numbers and accounts, but did not allege the details of the allegedly false representations or when they were made, and did not connect the alleged fraud to specific false claims. *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 47 (1st Cir. 2009); *see also United States ex rel. Carpenter v. Abbott Labs., Inc.*, 2010 WL 2802686, \*7 (D. Mass. July 16, 2010) (allegations that defendant offered or paid kickbacks to doctors to induce them to prescribe defendant's drug were insufficient under Rule 9(b) because complaint offered no particulars as to names, dates, amounts, or incentives that specific doctors were alleged to have been offered). Most recently, in *Duxbury*, the First Circuit held in a "close call" that a complaint was sufficient under Rule 9(b), but only because it identified eight specific providers by name and location who had allegedly submitted false claims for payment, and for each, provided dates and amounts of false claims, the government program to which those claims were submitted, and the name of the defendant's employee who allegedly provided the product at issue to the provider. *United States ex rel. Duxbury v. Ortho Biotech Prods., LP*, 579 F.3d 13, 30 (1st Cir. 2009). Here, Relator Laughlin not only did not allege any examples of any false claims with particularity, but he also did not even attempt to allege the circumstances of any fraud by Defendants with particularity. The SAC does not allege who engaged in any misconduct and with whom, when any misconduct allegedly occurred or where, or how any such specific conduct led to any particular false claims. Mot. to Dism. SAC at 4–6. Under *Karvelas*, *Gagne*, and *Duxbury*, Counts 1–5 and 7–56 of the SAC plainly must be dismissed.

Relator's Opposition does not challenge Defendants' contention that these First Circuit cases mandate dismissal of these Counts. Instead, the Relator ignores First Circuit law altogether, argues that this Court should apply a *completely different* standard, and supports this

contention by citing exclusively out-of-circuit case law. *See* Opp’n ¶¶ 34–37; *see e.g., United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 191 (5th Cir 2009) (noting that its analysis departs from First Circuit law). This case law not only acknowledges its departure from the First Circuit standard, but also applies standards that Relator’s complaint would *still* fail to satisfy. For example, Relator’s sparse factual allegations fall far short of the detailed pleadings in *Grubbs*, which described, with specificity, “the date, place, and participants” as well as the relator’s “first-hand experience” of the alleged fraud. *Grubbs*, 565 F.3d at 191–92. Relator Laughlin’s allegations similarly pale in comparison to the first-hand account of another relator’s own services being misbilled in *United States ex rel. Walker v. R & F Props. of Lake County, Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005), also cited by Relator. Opp’n ¶ 35. Finally, Relator’s suggestion that the strict particularity requirements laid out by the Eleventh Circuit in *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301 (11th Cir. 2002) apply only at summary judgment, not on a motion to dismiss, is simply incorrect. Opp’n ¶ 34. Although some courts in some circuits may have cited *Clausen* at summary judgment, *Clausen* itself involved a motion to dismiss, *Clausen*, 290 F.3d at 1305, and the First Circuit has cited *Clausen* at the motion to dismiss stage. *See, e.g., Karvelas*, 360 F.3d at, 233, 242–43 (citing *Clausen* and affirming grant of motion to dismiss).

Because Counts 1–5 and 7–56 fail to allege any FCA violation by Defendants with the specificity required by *Karvelas*, *Gagne*, *Duxbury* and other First Circuit decisions, these Counts of the SAC should be dismissed.

## **II. Counts 1–5 And 7–56 Should Be Dismissed Under Rule 12(b)(6) Because They Have No Basis In Law, Are Jurisdictionally Barred, Or Otherwise Fail To State A Claim**

In addition to failing to satisfy Rule 9(b), Counts 1–5 and 7–56 of the SAC fail to state a claim under Rule 12(b)(6). Count 1 is expressly barred by the FCA’s first-to-file rule and relies

on an alleged rental “requirement” that does not in fact exist. Counts 2 and 3 similarly depend on alleged legal requirements that simply do not exist, and Relator has effectively conceded the point by failing to argue otherwise in his Opposition. Counts 4–5 and 7–56 all fail to state a necessary legal element of their claims, or plead the claims in such general terms that they fail to meet even the requirements of Rule 8(a). For example, Relator used his leave to amend his first Amended Complaint to add dozens of state law counts (Counts 10–56), but did not allege any facts relating to those counts—he merely offered a description of the statutes under which he proposes to proceed. This is not enough to survive a motion to dismiss. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949–50 (2009) (holding that courts must disregard legal conclusions and consider only well-pleaded factual allegations). Accordingly, Counts 1–5 and 7–56 should be dismissed.

A. Count 1 Has No Basis in Law and Is Barred by the FCA’s First-To-File Rule

Relator continues to argue that Orthofix was required to bill its BGS units to government payers as a rental device based solely on a wholly inapplicable provision of law. Relator asserts, without citing supporting authority or other justification, that BGS are not reimbursed under the “inexpensive and other routinely purchased durable medical equipment” (“DME”) reimbursement category, 42 U.S.C. § 1395m(a)(2), but rather are reimbursed under the “other items” of DME category, § 1395m(a)(7). He then observes that § 1395m(a)(7) requires “other items” of DME to be rented. *See* Opp’n ¶¶ 21–24. His sole support for this is his assertion that BGS is not “inexpensive.” Opp’n ¶ 22. However, at all times relevant to this action, the federal Center for Medicare and Medicaid Services (“CMS”) had itself explicitly assigned BGS devices to the “inexpensive and other routinely purchased” category—which includes DME “acquired at least 75 percent of the time by purchase”—and had instructed DME suppliers like Defendants to seek reimbursement for BGS using this category. *See* 42 U.S.C. § 1395m(a)(2)(A)(ii); 42 C.F.R. § 414.220(a)(2); Program Memorandum, HCFA Transmittal AB-00-05, *Operating Instructions*

*for Expanded Coverage of the Electrical Osteogenic Stimulator for Fracture Healing I* (Feb. 2000), available at <http://www.cms.gov/transmittals/downloads/AB000560.pdf> (BGS part of “inexpensive and other routinely purchased” category). For items in this category, payment is “made on a rental basis or in a lump-sum amount for the purchase of the item.” 42 U.S.C. § 1395m(a)(2)(A); 42 C.F.R. § 414.220(b)(1) (emphasis added). Thus, CMS’s instruction to Defendants and other suppliers was expressly that BGS could be reimbursed as a purchase. As a result, Relator’s claim that Defendants were required to rent their BGS is contrary to CMS’s direction and has no basis in law. As a result, Count 1 should be dismissed.

More critically, however, the Court has no subject matter jurisdiction to hear Relator Laughlin’s rental-requirement claims in the first place, because an earlier relator—Jeffrey Bierman—alleged the same claims in a previously filed complaint, and the FCA allows only the *first* relator to pursue related claims on behalf of the United States. Mot. To Dism. SAC at 8–9. It is black letter law in the First Circuit and elsewhere that this bar is both jurisdictional and without exception. *Duxbury*, 579 F.3d at 16, 32–33. The only pertinent question is whether the claims in the later-filed complaint (Laughlin’s) allege the “same essential facts” or “elements” as the claims in the earlier-filed complaint (Bierman’s). *Id.* (emphasis omitted). If they do, the later-filed claims are barred and must be dismissed. Here, there is no real dispute that Relator Laughlin’s claims allege the same essential facts or elements as Relator Bierman’s claims. *See* Bierman Orig. Compl., 1:05-cv-10557 Dkt. No. 1, ¶¶ 45–55, 75–80; Laughlin Orig. Compl., 1:08-cv-11336 Dkt. No. 2, ¶¶ 24, 25, 30. Relator does not—and cannot—seriously contest this; in fact, he has, in the past, argued that his claims are so “intertwined” with the claims in the

Bierman complaint that the cases must be considered together on an identical schedule.<sup>2</sup>

Instead, defying logic and controlling law, Relator argues that he should be allowed to proceed because he is an “original source” of information and the claims he pleads were not “publicly disclosed,” even though he was *not* the first relator to allege them. Opp’n ¶¶ 31–33, 42–43. Relator is apparently conflating the exception-free “first-to-file” bar—established by § 3730(b)(5) of the FCA—with the entirely distinct “public disclosure” bar—established by § 3730(e)(4) of the FCA—which prohibits courts from exercising jurisdiction over suits based on certain publicly disclosed information unless the relator is an “original source” of information. *See* 31 U.S.C. § 3730(e)(4). The first-to-file bar, however, creates an independent limit on the court’s jurisdiction, entirely separate from the public disclosure bar. *See Duxbury*, 579 F.3d at 16. In other words, even if Relator managed to escape the public disclosure bar, his suit would still be foreclosed by the first-to-file rule.

Furthermore, Relator’s attempt to re-cast his complaint as a “separate” action under the recently amended version of the FCA is similarly misguided.<sup>3</sup> Opp’n ¶¶ 42–44 (section heading) (citing 31 U.S.C. § 3729(a)(1)(B)). Under the relevant provision, Relator’s SAC would still assert the same essential facts or elements included in Relator Bierman’s prior-filed complaints. Even if Relator pled new or additional details of an alleged scheme, including facts that did not appear in the prior-filed complaint, such allegations are insufficient to overcome the bar.

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<sup>2</sup> *See* Relator Laughlin’s Response to Def.’s Mot. For Leave To File a Reply and To Extend Time in Which To File an Opp’n to Relator Laughlin’s Mot. for Leave to Amend, Dkt. No. 114, ¶ 3.

<sup>3</sup> 31 U.S.C. 3729(a)(2) was amended in May, 2009 and renumbered 31 U.S.C. 3729(a)(1)(B). The changes to this section did not pertain to the FCA’s longstanding prohibition on a defendant’s use of a false record or statement, but instead focused on whether that false statement needed to be used to get a claim paid to trigger liability, or whether—as is now the law—it is sufficient that the defendant’s use of the false record or statement was material to a false claim. *See* 31 U.S.C.A. 3729(a)(1)(B) (2009).

*Duxbury*, 579 F.3d at 16, 33; *United States ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 218 (D.C. Cir. 2003) (“variations” on the fraud insufficient); *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1189 (9th Cir. 2001) (additional “details” insufficient). At base, Relator Laughlin’s claim that Orthofix made “false records or statements” in violation of the post-amendment False Claims Act, 31 U.S.C. § 3729(a)(1)(B) (2009), Opp’n ¶¶ 42–43, would remain indistinguishable from Relator Bierman’s claim that Orthofix made “false records or statements” in violation of the pre-amendment False Claims Act, 31 U.S.C. § 3729(a)(2) (2008), Bierman Orig. Compl. ¶¶ 77–78, 80. Because Relator cannot turn back the clock and file his claims before Relator Bierman, Count 1 is incurably foreclosed by the first-to-file bar and should be dismissed.

B. Counts 2 and 3 Should Be Dismissed Because Relator Effectively Concedes That They Have No Basis in Law

Counts 2 and 3 of the SAC are based entirely on Defendants’ alleged violation of supposed legal requirements that do not in fact exist. Defendants’ Motion to Dismiss clearly explained why these Counts have absolutely no basis in law. Mot. To Dism. SAC at 9–12. Relator’s Opposition does not challenge—or even address—Defendants’ arguments as to these Counts, and does not even attempt to identify any legal basis for these claims.<sup>4</sup> In short, Relator’s allegations that Orthofix failed to bill Medicare, Medicaid or TRICARE the lowest price it charged to any other customer, SAC ¶¶ 41, 44–45 (Count 2), or submitted claims to those entities without a contract for BGS or an individual billing code for Cervical-Stim, SAC ¶¶ 46–47 (Count 3), should be dismissed because there is simply no law requiring Orthofix to do

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<sup>4</sup> This is not the first time that Defendants have pointed out the complete absence of any legal basis for these Counts. After they appeared in Relator’s first Amended Complaint, Defendants moved to dismiss them on the same grounds asserted here, but Relator chose not to defend those Counts there either. See Def.’s Rep. to Rel. Resp. to Defendants’ Mot. to Dism., Dkt. No. 118, at 2–3.



otherwise, and Relator has not suggested or argued that there is one. Since Relator has failed to address this defect in his Opposition—and because the defect is in fact incurable—his claims under Counts 2 and 3 should be dismissed.

C. Counts 4–5, 7 and 10–56 Should Be Dismissed Because They Fail To Plead Necessary Facts or Elements of a Claim

As Defendants stated in their Motion to Dismiss, Relator did not plead, even in conclusory fashion, all the necessary elements of his kickback, conspiracy, and state law claims. Mot. To Dism. SAC at 12–14, 16–18 (addressing Counts 5, 7, and 10–56). Once again, Relator’s Opposition completely ignores Defendants’ arguments on these points, and offers no contest to dismissal of all of these claims on that basis. Thus, in Count 5, Relator generally alleges that Orthofix paid “Illegal Kickback[s]” to physicians, SAC ¶¶ 52–54, but did not allege that Orthofix knowingly and falsely certified compliance with the Anti-Kickback Statute (“AKS”)—a necessary prerequisite to converting an alleged AKS violation into an FCA claim. *See* Mot. To Dism. SAC at 12–13; *Karvelas*, 360 F.3d at 232, 234 (on their own, “alleged violations of federal regulations are insufficient to support a claim under the FCA”). Similarly, in Count 7 Relator alleged generally that Orthofix conspired with physicians to submit false claims, but did not allege the existence of a single agreement between Orthofix and any third party to pursue a wrongful end—a required element of any conspiracy claim under the FCA. *See* Mot. To Dism. SAC at 13–14; *see also Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005). Finally, in his Opposition, Relator does not even mention the tag-along state and municipal claims set forth in Counts 10–56, much less address the many defects in his pleading of those claims that Orthofix pointed out in its Motion to Dismiss. Relator’s failure to allege which state or local program requirements were allegedly violated, and to meet the numerous jurisdiction-specific

procedural requirements for bringing these state and local false claims actions remain fatal to these Counts. *See* Mot. To Dism. SAC at 16–18.

In addition, even where the SAC did address elements of the claims in Counts 4–5, 7, and 10–56, these Counts still should be dismissed under Rules 8(a) and 9(b), because Relator failed to plead basic facts that plausibly support his claims—instead he merely recited statutory elements and broad conclusory assertions. For example, Counts 5 and 10–56 simply parrot the relevant statutory language without offering any factual support, which is patently insufficient under any pleading standard. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Similarly, Relator fails to identify the Orthofix employees or third-party physicians allegedly involved in kickbacks or the submission of claims for fitting fees; any examples of such conduct; or any examples of false claims or statements allegedly submitted to each government payer at issue. Without such details, Relator’s allegations fail to state a valid claim. *See Iqbal*, 129 S. Ct. at 1949–50 (generalized allegations of misconduct do not suffice); *Karvelas*, 360 F.3d at 230, 232–35 (upholding dismissal under Rule 9(b) in absence of relevant details including, *inter alia*, the identify of those involved, the time and place of any misconduct, and why that particular claim was false); *Corsello*, 428 F.3d at 1014 (upholding dismissal of FCA conspiracy claim given lack of “specific allegations of any agreement” even though—unlike here—the parties to the alleged agreement were identified). Counts 4–5, 7, and 10–56 should therefore be dismissed.<sup>5</sup>

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<sup>5</sup> Under a September 10, 2010 letter to this Court, cc-ing Defendants’ counsel, Relator has provided certain “Exhibits” to his Opposition (the “Exhibits,” 1, 2 and A-F) that, among other things, describe efforts by the Defendants to identify and return overpayments to certain private payers. *See* Ex. B–D & 2. To the extent he intends to suggest that these exhibits augment the allegations in the SAC, he is mistaken. First, because the exhibits were not attached to the SAC that was filed and served in this case, they are not part of the complaint, and thus may not be relied upon to defeat Defendants’ Motion to Dismiss. *See Trans-Spec Truck Serv., Inc. v. Caterpillar Inc.*, 524 F.3d 315, 321 (1st Cir. 2008) (in reviewing a motion to dismiss, a “court may properly consider only facts and documents that are part of or incorporated into the complaint”). Second, to the degree the Exhibits even hint at any misconduct at all, they merely

### III. Relator's Retaliation Claim (Count 6) Should be Dismissed Because The Relator Has Not Alleged the Necessary Elements of An FCA Retaliation Claim

Under the FCA's retaliation provision, a relator must allege that (1) the relator engaged in "protected conduct;" (2) defendants knew of this protected conduct; and (3) defendants terminated the relator's employment because of his protected conduct. *Karvelas* 360 F.3d at 235. Under First Circuit law, the SAC does not sufficiently allege the required elements of an FCA retaliation claim, and Relator's Opposition offers no case law or other basis for allowing Count 6 to survive.

First, none of the three out-of-circuit cases cited in his Opposition supports Relator's assertion that the SAC alleges that he engaged in "protected conduct." While Relator need not have "developed a winning qui tam action," Opp'n ¶ 30, the First Circuit does require him to allege facts that plausibly show that his alleged conduct "reasonably could lead" to an FCA action. *Karvelas*, 360 F.3d at 237. The particular conduct that Relator refers to in his Opposition, however, Opp'n ¶¶ 26–30, like the rest of the SAC's attempts to allege "protected conduct," fall short of this standard. Instead of alleging any conduct by Relator, they describe conversations in which Relator's colleagues expressed concerns about certain conduct or practices or set out what certain colleagues happened to do in Relator's presence; and instead of addressing alleged false claims submitted to a government payer, they address alleged noncompliance with contracts with private payers. *See Karvelas*, 360 F.3d at 236–38 (requiring

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address returning overpayments owed to private payers. As the First Circuit has made clear, even a complaint that "amply describes illegal practices" will not survive a motion to dismiss if those practices do not involve claims for government payment. *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007); *see also Duxbury*, 579 F.3d at 29 (noting, in absence of particularized facts to the contrary, that relevant individuals may have treated federal payers differently, even if conduct related to private payers was improper); *Clausen*, 290 F.3d at 1311 (holding that relator may not "describe a private scheme in detail" and then simply allege that fraudulent claims "must have been submitted" to the government).

allegations of fraud on the government, and finding that a litany of activities—including reporting absence of quality control measures, inappropriate documentation of patient care, and failure to meet regulatory standards—were not activities that “reasonably could lead” to an FCA action); *Gublo v. NovaCare, Inc.*, 62 F.Supp. 2d 347, 356 (D. Mass 1999) (“[T]he plaintiff must demonstrate that her investigation, inquiries and/or testimony were directed at exposing a fraud upon the government.”). Nor do any of Relator’s Exhibits cure this defect (assuming, *arguendo*, they are properly before this Court to begin with).<sup>6</sup> To the degree any of the exhibits reflect any investigatory action actually taken by *Relator*, it is clear from the documents that that activity addressed only interactions with private payers, not any potential FCA violation.

Second, while Relator need not have formally announced his plans to launch an investigation, Opp’n ¶ 28, the First Circuit requires that a relator have provided notice to the defendant that he was engaging in protected activity. *Karvelas*, 360 F.3d at 239 (“What the employer must know is that the plaintiff is engaged in protected conduct, that is, investigation or other activity concerning false o[r] fraudulent claims that the employer knowingly presented to the federal government.”). Relator’s Opposition, however, does not point to any allegations in the SAC that show that Defendants knew he was engaged in any protected activity. Nor would any of the Exhibits Relator has attached to his Opposition cure this defect in his complaint. Even if the “Bette Datelle” email or other Exhibits that were allegedly circulated to “high ranking employees,” Opp’n ¶ 28, implied misconduct at all, they have nothing to do with any involvement in any alleged fraud on the government, but rather address the clarification and application of Defendants policies regarding overpayments by private payers. *See* Ex. B, C &

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<sup>6</sup> As set out *supra*, n. 5, Relator cannot rely upon these late-filed Exhibits to defeat Defendants’ Motion. To the degree this Reply discusses other Exhibits, *infra*, it similarly does so without conceding that they may properly be considered in weighing the merits of Defendants’ Motion.

D.<sup>7</sup> As a result, these emails can not have provided “notice” to Defendants that Relator was purportedly engaged in an investigation into whether Defendants were violating the FCA. *Karvelas*, 360 F.3d at 239. In addition, Relator’s contention that Orthofix somehow knew that Relator was purportedly engaged in protected conduct because one Orthofix employee told Relator that another Orthofix employee (who was not the Relator) was a “classic whistleblower” simply defies logic. Opp’n ¶ 29.

Finally, the SAC does not allege facts that plausibly support Relator’s conclusory assertion that the third element of an FCA retaliation claim has been satisfied—that he was terminated because he engaged in “protected conduct.” *See Karvelas*, 360 F.3d at 240 (dismissing an FCA wrongful termination claim because plaintiff had failed to “allege a factual predicate concrete enough to support his conclusory statement that he was retaliated against because of conduct protected under the FCA”).

The “Severance Agreement” (the “Agreement”) that Relator relies on to support his claim, Ex. E, cannot bear the weight he would put on it. While Relator insists—based on no more than the Agreement itself—that the Agreement was specifically intended to prohibit him from pursuing a whistleblower action or otherwise disclosing what his “investigation” had uncovered, Opp’n ¶¶ 27, 29, a careful reading of the Agreement reveals only general boilerplate releases of claims and confidentiality provisions. *See* Ex. E. Indeed, while the Agreement specifically refers to a litany of statutes and legal theories under which the prospective signee would not be able to recover, it conspicuously makes *no mention whatsoever* of the FCA, the Anti-Kickback Statute, or of *qui tam* suits in general. *Id.* Nor does the allegation that Relator

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<sup>7</sup> Indeed, none of the Exhibits mentions any interaction between the government and Orthofix, and the bulk of Exhibit D discusses the practices at a third-party company called “Integrated HomeCare,” not Orthofix.

received the Bette Datelle email, Ex. C, the same day he was terminated provide any support for this element of his claim. Opp’n ¶¶ 28–29. Even assuming that this court can properly consider the email (and Relator’s representation as to its date),<sup>8</sup> the email is irrelevant to any FCA retaliation claim, because it refers exclusively to interactions with private payers, and thus could not have provided a basis for retaliatory termination for investigating fraud against the government under the FCA. *Karvelas*, 360 F.3d at 240 (finding plaintiff’s allegations that he had been terminated for investigating conduct that was not in fact actionable under the FCA to be insufficient to support the causation element of plaintiff’s FCA retaliation claim).

#### **IV. Relator’s Motion To Amend Should Be Denied**

Over the course of this four-year-old case, Relator has had four separate opportunities to file a complaint that states a viable cause of action against Defendants with the specificity required by the Federal Rules. The SAC was crafted after the Relator had received full briefing by Defendants identifying the many fatal defects of Relator’s previous complaint and the pertinent legal standards that would apply to any subsequent complaint. Despite the opportunity to cure these defects and meet that standard, Relator’s SAC does neither. At this point, even Relator does not argue that he currently can plead additional facts to cure the deficiencies in his complaint, and his Motion for Leave to Amend should be denied. *See Foman v. Davis*, 371 U.S. 178, 182 (1962) (explaining that reasons for denying leave to amend include “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed . . . futility of amendment, etc.”); *Gagne*, 565 F.3d at 48 (citing *Foman*). To the extent Relator seeks leave to engage in civil discovery prior to amendment to cure the inadequacies of his pleadings, Opp’n ¶¶ 25, 52, clear First Circuit case law requires

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<sup>8</sup> The SAC included no allegation as to the date of the Datelle email. To the degree Exhibit C provides that information, it is not properly considered here, for the reasons noted *supra*, n. 5.

denial of this request. Relator's Motion for Leave to Amend should be denied, and the SAC should be dismissed with prejudice.

A. Amendment Would Be Futile

Counts 1–3 cannot be cured no matter how many opportunities Relator is offered. As set out *supra*, Part II.A–B, there is no legal basis for these Counts, and Count 1 is jurisdictionally barred. As to the remaining Counts, Relator has already had four distinct opportunities to meet the pleading requirements of the Federal Rules—his initial complaint, his Amended Complaint, the opportunity (albeit ultimately declined) to amend prior to service on Defendants, and the SAC at issue here<sup>9</sup>—and has failed each time, most recently after Orthofix set out the Amended Complaint's specific failings.<sup>10</sup> Indeed, by now seeking discovery prior to still further amendment, Relator essentially concedes that he is currently unable to author an adequate pleading. Under these circumstances, leave to replead yet again would be futile, and should be denied. *See Gagne*, 565 F.3d at 48 (affirming lower court's denial of leave to file third amended complaint, which was “based on relators’ repeated failure to cure the deficiencies in their pleadings,” and noting that “[p]laintiffs do not get a fourth chance to try to get it right”); *Corsello*, 428 F.3d at 1014–15 (affirming denial of leave to file third amended complaint, citing plaintiff's repeated failure, despite prior warnings, to cure Rule 9(b) deficiencies in past amendments).

The First Circuit and the Supreme Court have expressly and consistently held that plaintiffs and Relators may not take civil discovery to cure a complaint that otherwise fails to

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<sup>9</sup> Indeed, to the degree the September 10, 2010 letter and its Exhibits was in fact an effort to amend the SAC, Relator has attempted to effect a fifth, albeit procedurally improper, amendment—and as set out *supra*, this one too is insufficient.

<sup>10</sup> *See, e.g.*, Def.'s Mot. to Dism. Rel.'s Am. Compl., Dkt. No. 91; Def.'s Reply to Rel.'s Resp. to Def.'s Mot. to Dism., Dkt. No. 118.

meet the requirements of Rules 8 and 9(b). *See Ashcroft v. Iqbal*, 129 S. Ct. at 1953–54 (“Because respondent’s complaint is deficient under Rule 8, he is not entitled to discovery, cabined or otherwise.”); *Karvelas*, 360 F.3d at 231 (“[W]e hold that a qui tam relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery.”); *United States ex rel. Rost v. Pfizer*, 507 F.3d 720, 733 (1st Cir. 2007) (“[T]he rule discourages plaintiffs from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlement.”); *United States ex rel. Joshi v. St. Luke’s Hosp, Inc.*, 441 F.3d 552, 559–61 (8th Cir. 2006) (denying Relator’s “request to permit discovery to satisfy Rule 9(b)”; *United States ex rel. Driscoll v. Serono, Inc.*, Civ. No. 00-11680, 2008 WL 728939, at \*3 (D. Mass. Mar. 18, 2008) (denying request to seek discovery in order to plead with required particularity, noting that the First Circuit has “expressly discouraged the use of discovery by relators to obtain details of actual false claims when they have only made general, that is, not particularized, allegations in their complaint”).<sup>11</sup> Where, as here, Relator has repeatedly failed to file an adequate complaint, and has conceded that his only means for doing so is discovery—an avenue that is foreclosed by law—amendment would be futile.

B. Amendment Would Reward Undue Delay

Allowing further amendment would not only be futile, but would also reward a relator whose procedural history reflects deliberate efforts to delay adjudication of his complaint. First,

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<sup>11</sup> Laughlin complains that the government has precluded him from “conduct[ing] discovery.” Opp’n ¶ 2. As a relator, he brought this case on the government’s behalf. *Karvelas*, 360 F.3d at 231 (noting that the government, “of course, [is] the real party in interest in a qui tam action”). Even if the government had exercised its statutory right to seek to intervene and prevent Relator from conducting discovery, *see* 31 U.S. C. § 3730(b)–(c)—which it has not—Relator is not entitled to discovery to meet his pleading burden under First Circuit law.



despite Orthofix's stated concerns about this very issue,<sup>12</sup> Relator used his SAC solely to add factual allegations that could have been included in Relator's Amended Complaint, if not in the original complaint itself, and to add forty-seven new boilerplate state and local false claims act Counts that Relator did not make any effort to substantiate. Second, Relator did not timely file his Opposition to Defendants' Motion to Dismiss the SAC. Instead, after first seeking an extension from Defendants' counsel nine days after that deadline had passed, Relator finally filed his Opposition, without leave of Court, on September 10<sup>13</sup>—an Opposition that was, with the exception of a handful of amended paragraphs and a reordering of its Argument sections, identical to the response Relator filed to Orthofix's Motion to Dismiss Relator's prior Amended Complaint. *Compare* Opposition with Resp. to Mot. to Dism. and Mot. for Leave to Am., Dkt. No. 102. Finally, despite having first referred to certain "exhibits" in his May 7, 2010 briefing regarding Defendants' Motion to Dismiss the Relator's Amended Complaint—and Defendants having repeatedly noted their absence in numerous subsequent filings<sup>14</sup>—Relator did not provide any exhibits to Defendants until over four months after he first cited to them. This dilatory approach should not be rewarded, and is grounds for denying leave to amend. *See Gagne*, 565 F.3d at 48 ("Reasons for denying leave include undue delay . . . or dilatory motive . . ."); *Hayes v. New England Millwork Distribs., Inc.*, 602 F.2d 15, 19–20 (1st Cir. 1979) (holding, following

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<sup>12</sup> See Def.'s Opp'n to Rel.'s Mot. For Leave To Am. Compl., Dkt. No. 116, at 15-16.

<sup>13</sup> Relator's Opposition was due August 23, 2010, per this Court's June 9, 2010 Order, Dkt. No. 120. This deadline passed without any opposition being filed. On September 1, 2010, Relator's counsel asked Defendants' counsel to agree to an extension of Relator's deadline. Counsel for Defendants agreed not to oppose an extension to September 10, 2010, at which point Relator filed his Opposition, but without seeking leave for this late filing from the Court.

<sup>14</sup> See Def.'s Opp'n to Rel.'s Mot. for Leave To Am., Dkt. No. 116, at 2, n.1; Def.'s Reply to Rel.'s Resp. to Def.'s Mot. To Dism., Dkt. No. 118, at 2, n.1; Def.'s Mot. To Dism. Rel.'s SAC, Dkt. No. 127, at 2, n. 3.

years of briefing and discovery, “where, as here, a considerable period of time has passed between the filing of the complaint and the motion to amend . . . the movant [must] show some ‘valid reason for his neglect and delay’”); *Driscoll*, 2008 WL 728939, at \*4 & n.2 (refusing leave to amend where relators had been on notice of *Karvelas*’ Rule 9(b) standard, and had failed to allege sufficient detail to meet Rule 9(b) despite having years, and subsequent amended complaints, to do so).

### CONCLUSION

For the reasons set out above, Relator’s Second Amended Complaint should be dismissed with prejudice, and his Motion for Leave to Amend denied.

Dated: October 1, 2010

Respectfully submitted,

DEFENDANTS

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**CERTIFICATE OF SERVICE**

I hereby certify that these documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non registered participants on October 1, 2010.

Dated: October 1, 2010

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